Sterilization Cassette Systems, Inc.
MEDICAL · DENTAL · LABORATORY

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Docket # 02D-0039
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and management Services
Food and Drug Administration
5639 Fischers Lane, Room 1061, (HFA-305)
Rockville, MD 20852

Dear Sirs:

The following are the comments and recommendations for consideration for Docket # 02D-0039, Premarket Notification [510-(k)], Submissions for Medical Sterilization Packaging systems in Health Care Facilities; Draft Guidance for Industry and FDA

1. I. Introduction – last sentence, 1st paragraph – This guidance document also covers reusable cassettes, containers, case/tray systems, and trays provided by instrument manufacturers that are represented as effective in the terminal sterilization process for reusable/disposable instruments by the health care facility.
2. I. Introduction – 3rd bullet point – Sterilization containers, case/tray systems, organizing trays and cassettes .....Rationale – the orthopedic community commonly refers to their packaging for instrument sets as instrument container, instrument tray, instrument case/tray system so consideration for this change throughout the document may be justified. The term "instrument cassette" is more common to the dental industry and small surgical sets, e.g. microsurgery, ENT, etc.
3. I. Introduction – C. Definitions – Cassettes, Sterilization – A distinction between a sterilization container and a sterilization cassette goes back to 1985 and the first dental cassettes. Dental cassettes serve a dual purpose; they must have sufficient surface perforations to be compatible with ultrasonic cleaners when unwrapped, generally 30-45% open area, which means that the instruments inside the cassette can be adequately cleaned without hand scrubbing or being touched by the assistants, and then they are wrapped for steam sterilization. A definition for consideration could be, FDA classifies cassettes as sterilization containers that are designed with large surface open areas in order to be compatible with both ultrasonic cleaners and health care sterilization systems. To maintain sterility, they are enclosed in a sterilization wrap.
4. I. Introduction – C. Definitions - Case/Tray Systems, Sterilization This would follow Cassettes, Sterilization – A perforated tray set consisting of a base, a lid and multiple trays designed to organize and process medical devices or instrument

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sets through specific health care facility sterilization processes. These systems may be generic designs to organize and process loose instruments or devices through the cleaning and sterilization process or they may be custom designs to organize instruments or devices from instrument/orthopedic manufacturers that are also designed for the health care facilities cleaning and sterilization process. To maintain sterility, they are enclosed in a sterilization wrap.

5. I. Introduction – C. Definitions - definition of Trays – FDA defines trays as a rigid platform designed to hold or organize instruments or devices that may be wrapped separately with sterilization wrap to, maintain sterility or that may be placed either inside a rigid sterilization container with a sterilization filter or inside a sterilization case/tray system that would be enclosed in a sterilization wrap to maintain sterility. Trays include metal perforated and wire basket designs as well as thermoformed and injected molded polymer designs.
6. I. Introduction – F. Device Modification – 2nd paragraph - ....do not require submission of a new 510 (k). This does not apply to a preenactment device that does not have documented sterilization validation testing and appropriate labeling and instructions for health care facilities or to a preenactment device that has changed or added claims for sterilization compatibility after the passage of the Medical Device Act and has not submitted a Class II 510 (k) to the FDA. I would recommend discussing this point with Chiu Lin PhD. Of the Office of Device Evaluation. I expressed my concern about allowing adulterated products to continue to be sold solely because they were marketed before May 28, 1976. Chiu Lin assured me this would not be allowed at a recent AAMI meeting so he may have the best definition or caveat for this point.
7. II. 510 (k) Content – C. Information Required – 5th paragraph – Throughout this document there should be consistency for one of the key goals of the guidance document; the validated performance of sterilization containers, cassettes and case/tray systems with standard hospital sterilization cycles. Without this language, companies with non-standard sterilization cycles will have no reason to change. An Indication for Use Statement for a sterilization packaging system should include documentation of the manufacturer's test methodology. The results shall include information verifying that the sterilization efficacy of the sterilization packaging system has been qualified in published standard hospital sterilization cycles and has passed standard AAMI (or equivalent) challenge tests for each method of sterilization for which the container system, cassette, organizing tray or case/tray system is labeled (Standard Hospital Sterilization Cycles are published in Appendix H). If it is not possible to qualify a sterilization cycle using parameters given in Appendix H, it is recommended that the manufacturer adjust those parameters that health care personnel can control without causing damage or destruction to other medical devices that would be processed in the same sterilization load. An update of Annex B in AAMI TIR-12 would suffice for Appendix H. I have attached the current published standard autoclave cycles for Steris/AMSCO and Gettinge/Castle. It is important to recognize that an extended steam cycle that exceeds the recommended 3-4 minute standard cycle may damage certain reusable products like scopes. Rigid and flexible scopes have only recently had design upgrades to permit standard steam

sterilization cycles. These products, however, could be damaged or destroyed in an 8-12 minute steam cycle. The potential damage to other products and devices validated only for standard autoclave cycles is justification to insist on compatibility for all products with the standard sterilization cycles of the sterilization instrument manufacturers. The redesign of a device or the selection of an alternative sterilization process is preferred over the suggestion that a hospital should change a published standard cycle for a product that cannot be validated in a standard cycle.

8. II. – 510 (k) Content – D. - Sterilant Penetration – You should submit performance data comparing the characteristics of sterilant penetration of your device with the predicate. You must document that the perforations plus filter paper of a rigid container (plastic, metal or hybrid design) or that the perforations of the cassette, organizing tray or case/tray system (plastic, metal or hybrid design) plus the sterilization wrap are sufficient to achieve terminal sterilization of the contents of the sterilization packaging system by the recommended method of sterilization.
9. II, 510 (k) Content – D. - Microbial Barrier Properties – You should.....To maintain sterility, the sterilization packaging system must have a documented FDA approved microbial filter system or be enclosed by an FDA approved sterilization wrap.
10. II. 510 (k) Content – D. - Drying Time – You should submit.....It is recommended that your device should be compatible with published standard hospital sterilization cycle drying times found in Appendix H to eliminate "wet packs" an associated infection control problems. If it is not possible to qualify a drying cycle using the parameters in Appendix H, it is recommended that the manufacturer adjust those parameters that health care personnel can control. An example would be an extended drying time.
11. II. 510 (k) Content – E. – Material Composition – bullet point #3 - Sterilization containers, cassettes or trays – e.g. polymer, anodized aluminum, stainless steel, plastic & metal hybrids and nylon coated metal.
12. II. 510 (k) Content – F. – 2nd paragraph – Materials intended to wrap, containerize or seal articles being sterilized need to be validated and qualified in standard hospital sterilization cycles listed in Appendix H. and be approved by the FDA.....paragraph 3 – Sterilization cassettes need to be completely enclosed in sterilization wrap or placed in a rigid sterilization container with a filter to maintain sterility.....paragraph 4 – Sterilization trays or baskets are not enclosed systems. Generally, trays and baskets do not have lids. Instead, they may be entirely open. Therefore, sterilization trays and baskets need sterilization wrap to maintain sterility.
13. III. Performance Information and Testing – Protocol section – bullet #2, add Sterrad to sterilization methods.....bullet #3, Documentation of compatibility with standard hospital sterilization cycles listed in Appendix H or the alternative sterilization cycles tested .....Bullet # 7, Documentation of maximum weight of device or instrument set in compliance with standard hospital sterilization cycle maximum weight limits listed in Appendix H. If the manufacturer exceeds the standard maximum weight standards, it must document the effect on the

sterilization cycle and validate the remedy to achieve terminal sterilization of this specific instrument set or device.

14. III. Performance Information and Testing – A-3 – You should use up to the maximum recommended loads of instruments and configurations published in the standard hospital sterilization cycle operating instructions listed in Appendix H for you performance testing.....A-4 – Biological indicators (BIs) should be placed in the most difficult areas to reach.....by lethality of the BIs. These include placement of BIs inside lumens, between silicone instrument retainers and instruments when snapped into position, between closed jaws or instrument tips that cannot be processed in the open position, between plastic/polymer handles, trials or instruments and the brackets or troughs that hold these devices in place and in open crevices or internal space of instruments or devices with multiple parts that are processed in the assembled position.....the final sentence of paragraph 4 should refer to published standards in Appendix H.
15. III. Performance Information and Testing – D.1 - Drying Time - Testing should demonstrate that the sterilization packaging system permits drying of the medical instruments inside the package within the published standard sterilization drying time listed in Appendix H.....D.3 – A plastic container with and without a non-woven liner (stay consistent in the paragraph)

This concludes our comments about the guidance document. Consistency throughout the document will eliminate confusion and increase compliance. Please contact me if you have any questions about suggestions or references.

Sincerely,

Stephen F. Spencer
Chairman & CEO